

Written Testimony of
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Chairman Lautenberg, Ranking Member Vitter, and Members of the Subcommittee, my name is Joseph K. Doss. I am President and CEO of the International Bottled Water Association (IBWA)¹ in Alexandria, Virginia. Thank you for the opportunity to present this testimony on the quality of bottled water and the environmental impacts of bottled water.

Overview of the Bottled Water Industry

IBWA appreciates the opportunity to provide the Subcommittee with our views on the very important issues being considered at this hearing. Bottled water is a safe, convenient, healthful packaged beverage product that consumers find refreshing and use to stay hydrated. In many instances, consumers choose bottled water because it does not have the calories, caffeine, or other ingredients that they may wish to eliminate or moderate in their diets. And with the rise in obesity and diabetes in the United States, any actions that discourage the consumption of bottled water are not in the public interest.

The bottled water industry is the second largest commercial beverage category by volume in the United States. Nearly all bottled water sold in the U.S. is sourced domestically. Only 2.1% of the total volume is comprised of imported bottled water. According to the Beverage Marketing Corporation, in 2007, the total volume of bottled water consumed in the United States was 8.8 billion gallons, a 6.9% increase over the 2006 volume level. That translates into an average of 29.3 gallons per person, which means U.S. residents now drink more bottled water annually than any other beverage except carbonated soft drinks (CSDs). Sales revenues for the United States bottled water market in 2007 were approximately \$11.7 billion (in wholesale dollars), a 7.8% increase over the previous year. Although bottled water is currently the second most consumed

¹ IBWA is the trade association representing all segments of the bottled water industry, including spring, artesian, mineral, sparkling, well, groundwater and purified bottled waters. Founded in 1958, IBWA member companies include United States and international bottlers, distributors and suppliers. Bottled water companies produce a packaged food product that is comprehensively and stringently regulated by the United States Food and Drug Administration (FDA). IBWA is committed to working with state and federal governments to establish and implement stringent standards for assuring the production and sale of safe, high-quality bottled water products. In furtherance of this objective, IBWA has developed and published a Code of Practice (available at IBWA's website: http://www.bottledwater.org/public/policies_main.html), which establishes standards of bottled water production, quality, and distribution that must be met by IBWA members. In some cases, the IBWA Code of Practice is even more stringent than state and federal regulations. As a condition of membership, IBWA bottlers must submit to an annual, unannounced plant inspection by an independent third party to determine compliance with the Code of Practice and all applicable FDA regulations.

beverage in the United States, the consumption volume is about half that of carbonated soft drinks (CSDs) and only slightly ahead of milk and beer.

Based on this data, it is apparent that consumers are choosing bottled water in greater and greater numbers. The U.S. bottled water market is truly a consumer driven market, in which consumers are making healthier choices in the beverage category. The strength of consumer self-generated demand is illustrated by the relatively modest amount spent on bottled water advertising. The 2006 bottled water advertising expenses totaled only \$52 million.² For comparison purposes, \$637 million was spent on advertising for carbonated soft drinks (over ten times that for bottled water) and advertising expenses for beer totaled \$1 billion (approximately 20 times that for bottled water).

Bottled Water Industry Profile

The bottled water industry can be divided into two primary business models. The first model is the home and office delivery (HOD) of the three and five gallon bottles used with water coolers, which accounts for about 20% of the bottled water market. This segment of the bottled water market has been providing consumers with safe, quality products for over one hundred years in the United States. The second model is retail sales of bottled water to consumers in 2 ½ gallon, 1 gallon, and smaller sized bottles (e.g., half liter and liter), generally through convenience and grocery stores, as well as vending machines. Retail business accounts for about 80% of the bottled water market and is the largest and fastest growing segment of the United States bottled water industry.

The types of bottled water that comprise the United States market can be divided into two fundamental categories, which are aligned with the Food and Drug Administration's (FDA) standards of identity. The largest segment of the bottled water industry is sourced from groundwater. They are artesian, mineral, sparkling, spring and well water. The remainder of the market is processed water, such as purified, sterile or drinking water. Groundwater sources, which are used by an estimated two-thirds of bottled water companies, are exclusively from underground aquifers, while processed waters are either groundwater or water from municipal water systems.

Bottlers of natural waters have extensive investments in developing groundwater sources and have been on the forefront of advocating for states to enact groundwater management programs to provide sustainability of the resource. From the source, the water is moved to the bottling plant, whether by tanker truck or pipe, where, if needed for added safety, it is disinfected. The water is then placed in a sealed sanitary container in the filling room of the bottling plant. This process is also similar, if the bottling source is a public water system, with the exception of the added processing steps that are employed to meet the purified or sterile standard of the U.S. Pharmacopeia 23rd Revision, i.e. distillation, reverse osmosis, or de-ionization.

² Beverage Marketing Corp.

Bottled water companies in the United States are primarily family owned and operated small businesses. Over 60% of the IBWA bottler members have annual sales of less than \$1 million and 90% have sales less than \$10 million. Almost all bottled water brands are sold on a local or regional basis with the exception of imports and purified waters.

Bottled Water is a Regulated Food Product

Bottled water is comprehensively and stringently regulated in the United States at both the federal and state levels, which helps ensure its safety and quality. At the federal level, bottled water is regulated as a packaged food product by the FDA under the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. §§ 301 *et seq.*, and several parts of Title 21 of the Code of Federal Regulations (CFR). It must meet FDA's general food regulations as well as standards of identity, standards of quality, good manufacturing practices and labeling requirements specifically promulgated for bottled water.

The FFDCA defines “food” as “articles used for food *or drink* for man or other animals”³ Thus, all food and beverage products are regulated under the same statutory regime, and bottled water is no different in this respect than juice, carbonated soda, or energy drinks. Bottled water is subject to the same general prohibitions against adulteration and misbranding as other beverage products, and is subject to the same general requirements for ingredient labeling, nutrition labeling, and product claims as other beverage products, as well as good manufacturing practices. From a market and legal perspective, bottled water is the same as other beverages such as soft drinks, teas, and juices, which also have water as their primary ingredient.

FDA regulations define bottled water as “water that is intended for human consumption and that is sealed in bottles or other containers with no added ingredients except that it may optionally contain safe and suitable antimicrobial agents.” Fluoride may be optionally added within the limitations established in § 165.110(b)(4)(ii).⁴ As a result, bottled water is subject to the general Good Manufacturing Practices (GMP) and labeling regulations for all food products,⁵ as well as the specific bottled water GMPs in 21 CFR 129, and the FDA-established Standards of Quality and Identity in 21 CFR Part 165. Bottled water is one of only a few food products that must follow additional, product-specific GMPs in addition to the general food GMPs, as well as product-specific Standards of Quality and Identity.

FDA has promulgated Standards of Identity regulations that define what a given food product is, its name, and ingredients that must be used, or may be used in the manufacture of the food. In 1995, FDA established standard of identity regulations for bottled water. The Standard of Identity encompasses (1) a general description of bottled water; (2) names that may be used to identify bottled water products and what the terms mean (e.g., “bottled water,” “drinking water,” or alternative terms such as “purified water” or “spring water”); and (3) FDA requirements for “other label statements” specific to bottled water products. 21 C.F.R. § 165.110 (a) contains the

³ 21 U.S.C. § 321(f) (emphasis added).

⁴ 21 C.F.R. § 165.110 (a)

⁵ 21 C.F.R. § 110.3 *et seq.*

standard of identity for bottled water. It provides uniform definitions for the following bottled water classifications: bottled, drinking, artesian, groundwater, distilled, deionized, reverse osmosis, mineral, purified, sparkling, spring, sterile and well water. A bottled water product must meet the appropriate Standard of Identity and bear the required name on its label or it may be deemed misbranded under the FFDCA.⁶ By law, FDA's standards of identity regulations pre-empt state laws that are different from the FDA regulations.⁷ If a bottled water product's source is a municipal water system and it does not meet the FDA Standard of Identity for purified or sterile water, it must indicate on the label that it comes from a public water system source.⁸

Bottled water containers, as with all food packaging materials, must be made from FDA-approved food contact substances. Thus, the plastic and glass containers that are used for bottled water products have undergone FDA scrutiny prior to being available for use in the market place. FDA has determined that the containers used by the bottled water industry are safe for use with food and beverage products, including bottled water, and that they do not pose a health risk to consumers. FDA is continually reviewing published scientific studies on food contact substances and also working with other federal and international agencies in research on health impacts for a variety of subsets of the general population. FDA has rigorous standards for research and evaluation of risk for food contact substances. The bottled water industry and others in the food industry rely on FDA to evaluate and determine which substances are safe to be used in contact with food. All of the bottled water industry's packaging containers have been determined to be safe by FDA.

Bottled Water Quality

FDA establishes standards of quality regulations that set the allowable levels of substances that may be in a given food product. 21 C.F.R. § 165.110(b) contains the FDA Standards of Quality for bottled water. This regulation goes on for many pages and establishes quantifiable limits for microbiological, physical, chemical, and radiological substances for both source water and finished bottled water products. FDA has established standards for more than 90 substances pursuant to the Standard of Quality for bottled water. As FDA explained in its final rule amending the Standard of Quality for arsenic, the standard of quality regulations for bottled water are issued under the authority of the Standards of Identity and, therefore, pre-empt state laws that conflict with the FDA Standards of Quality.⁹

Most FDA bottled water quality standards are the same as EPA's maximum contaminant levels (MCL) for public water systems. In fact, by law, unless FDA determines that controlling for a particular contaminant is not applicable to bottled water (because, for example, the contaminant is not found in bottled water sources), FDA's Standard of Quality for any given contaminant must be as stringent and as protective of the public health as the corresponding EPA regulation for tap water. The few differences are usually the result of the substance not being found in

⁶ 21 U.S.C. § 343(g)(1).

⁷ 21 U.S.C. § 343-1(a)(1)

⁸ 21 C.F.R. § 165.110 (b)(3)

⁹ Beverages: Bottled Water, 70 Fed. Reg. § 33694, 33699- 33700 (2005).

bottled water or the substance is regulated under FDA food additives program.¹⁰ And, in some instances, FDA bottled water Standards of Quality are more stringent than EPA's public drinking water standards (e.g., copper, fluoride, lead, nickel and phenols).

(Note: A complete list and a comparison of the FDA standards of quality for bottled water, the EPA maximum contaminant levels (MCL), and the IBWA standards of quality can be found in the attached Appendix A of the IBWA Code of Practice.)

Section 410 of FFDCA requires FDA to review all U.S. Environmental Protection Agency (EPA) National Primary Drinking Water Standards (NPDWS) for public water systems to determine their applicability to bottled water. If FDA determines that the NPDWS is applicable to bottled water, it must establish standards of quality for bottled water that are as stringent and protective of public health as the EPA's standards for public drinking water. If FDA fails to act within 180 days of the effective date of any new EPA NPDWS for public water systems, FDA must then apply the new NPDWS to bottled water.

As noted, Section 410 of the FFDCA, was enacted by Congress to ensure that FDA's regulation of bottled water is at least as protective of the public health as EPA's regulation of public water systems.¹¹ Key elements include:

- a) Under Section 410, whenever EPA issues a primary drinking water regulation under section 1412 of the Safe Drinking Water Act that establishes a "maximum contaminant level" (MCL) or "treatment technique" for a contaminant, FDA is required to either: (a) publish a standard of quality for that contaminant for bottled water; or (b) make a finding that such a regulation is not necessary to protect the public health because the contaminant is contained in water in public water systems but not in water used for bottled drinking water.
- b) FDA is required to publish either the standard of quality or the finding that such regulation is not necessary not later than 180 days before the EPA regulation becomes effective. If FDA fails to act within that time, then the MCL's and/or treatment techniques established by the EPA become applicable to bottled water as a matter of law. If this happens, FDA – not EPA – would be responsible for enforcing the EPA standard or treatment technique made applicable to bottled water by operation of law.
- c) As noted above, the purpose of Section 410 is to ensure that bottled water is regulated at least as stringently as public water systems. If EPA sets an MCL, and FDA determines that such MCL is applicable to bottled water, then FDA is required to set a level that is "no less stringent" than the MCL set by EPA. Similarly, if EPA establishes a treatment technique, and FDA determines that such treatment technique

¹⁰FDA did not establish an allowable level for acrylamide and epichlorohydrin because EPA determined that establishing MCLs for these chemicals (used as flocculents in public drinking water) was not feasible, and because FDA regulations issued under the Food Additives Amendment of 1958 (Pub. L. 85-929) prohibit unsafe use of acrylamide and epichlorohydrin (as flocculents) in the production of bottled water. Regulations governing food additives can be found in 21 C.F.R. §§170-180. See 21 U.S.C. §§ 348(c)(3)(A).

¹¹ Federal Food, Drug, and Cosmetic Act § 410, 21 U.S.C. § 349 (2005).

is applicable to bottled water, then FDA is required to set requirements “no less protective of the public health” than the treatment technique established by EPA.

Three examples of how Section 410 has operated follow:

- a) FDA establishes a standard of quality regulation. FDA promulgated a regulation establishing a standard of quality for arsenic of 10 ppb on June 9, 2005,¹² which became effective on January 23, 2006. This was in response to EPA’s issuance of a revised arsenic standard for public water systems – at the same level of 10 ppb - that also became effective on January 23, 2006.¹³
- b) FDA takes no action. Following EPA’s issuance of MCL’s and monitoring requirements for nine contaminants (antimony, beryllium, cyanide, nickel, thallium, diquat, endothall, glyphosate, and 2,3,7,8-TCDD (dioxin), FDA did not amend its Standard of Quality regulations before the statutory deadline.¹⁴ In that case, Section 410 operated and the MCL’s established by EPA, as well as, the monitoring requirements, became applicable to bottled water, as a matter of law.¹⁵ This is the only occasion where FDA has not acted within the statutory timeframe.
- c) FDA determines EPA action not applicable to bottled water. After reviewing EPA’s Interim Enhanced Surface Water Treatment Rule (IESWTR), FDA concluded in a *Federal Register* notice on July 5, 2001,¹⁶ that it would not apply to bottled water, because bottled water is produced either from groundwater sources that are not under the influence of surface water or from municipal water systems that would have already complied with the IESWTR.

If pathogenic microorganisms are present in bottled water and potentially injurious to public health, FDA has authority to classify the product as adulterated¹⁷ and subject it to enforcement action, such as seizure of the product.¹⁸ This would apply to such microorganisms as *Cryptosporidium*, *Legionella*, *Giardia*, and other micro-organisms and viruses that are generally found in surface water. However, the Agency has not established standards of quality for these three microorganisms because bottled water is produced from either groundwater sources that, by definition, must not be under the influence of surface water,¹⁹ or from municipal water systems that are already compliant with EPA’s Surface Water Treatment Rule.²⁰

The FDA Standards of Quality for bottled water as contained in 21 C.F.R. § 165.110 (b) apply to all containers of bottled water sold in the United States. There are no waivers, or averaging of

¹² Beverages: Bottled Water, 70 Fed. Reg. § 33694 (2005)

¹³ National Primary Drinking Water Regulations; Arsenic and Clarifications to Compliance and New Source Contaminants Monitoring, 66 Fed. Reg. § 6976 (2001)

¹⁴ 63 Fed. Reg. § 25764

¹⁵ Bottled Water: Monitoring Requirements, 63 Fed. Reg. § 42199 (1998).

¹⁶ Beverages: Bottled Water, 66 Fed. Reg. § 35439 (2001).

¹⁷ 21 U.S.C. § 342.

¹⁸ 21 U.S.C § 334.

¹⁹ 21 C.F.R. 165.110 (a)(2)(ii)

²⁰ National Primary Drinking Water Regulations: Long Term 2 Enhanced Surface Water Treatment Rule, 71 Fed. Reg. § 653 (2006).

test results, or exemptions to the standards. Since the bottled water standards of quality apply to each container of bottled water, anyone is able to have an analysis done on bottled water and determine if it meets those standards. This is very different from public water systems, where you cannot take a sample from your faucet and have it analyzed to determine compliance with the public drinking water standards. Most public water system testing standards apply to the point of distribution and not the point of consumption. In addition, public water systems are permitted to average test results for most contaminants over a 12 month period to determine compliance and are often granted waivers.

Monitoring Regulatory Differences Between Bottled Water and Drinking Water

Bottled water is frequently tested throughout its production. To get an accurate picture and comparison of the frequency of testing between bottled water and municipal water systems, one should examine volume produced, or better yet, consumed. The entire bottled water industry in the United States annually produces approximately the same volume of water as a city of 150,000 people uses in the same time period. In addition, bottled water companies do not have waivers or exceptions available to them, as public water systems do.

For coliform testing, for example, the City of New York produces 1.086 billion gallons of tap water per day and is required to perform a minimum of 480 microbiologic tests, which represents one test per 67.875 million gallons produced. If coliform testing for bottled water was done on a volume basis, a large bottler producing 250,000 gallons per day would be required to perform at least one microbiological test per 1.875 million gallons or over 30 times as many tests per gallon of water than a public water system.

A comparison of chemical testing yields similar conclusions when frequency in terms of volume of water is considered. The National Primary Drinking Water Regulations (NPDWRs) provide a public water system that uses groundwater with opportunities for monitoring exemptions and reductions in testing frequency. FDA does not permit reduction of testing frequency to less than once per year, unless a state having jurisdiction over bottled water specifically issues such a waiver or reduction in monitoring. For example, for inorganic chemicals such as arsenic, cadmium, chromium, and mercury, a municipal water system with a groundwater source may receive permission from a state for a reduction in monitoring from every year to once every three or even nine years. Ironically, the only time that the same municipal water system source monitors for these chemicals more frequently than a bottled water source is when the municipal water system exceeds the MCL for any of the chemicals, at which time the NPDWRs require four consecutive quarters of testing for the chemical to demonstrate compliance with the MCL before a reduction can be considered again. Bottled water must be tested for these same chemicals annually, without any opportunity to request a reduction in testing frequency from FDA. In terms of comparing volumes, a municipal water system that distributes 5 million gallons of water per day and tests for inorganic chemicals every three years would test one sample for every 5.475 billion gallons of water. If the frequency is reduced to every nine years, the municipal water system would test one sample for every 16.425 billion gallons of water. The bottled water facility described above would test for the same inorganic chemicals every 91.25

million gallons, or over 50 times as many test per gallon of water, with no reduction in monitoring frequency under FDA’s regulations.

Most states have issued statewide or use waivers for certain synthetic organic chemicals (SOCs) for municipal water system source waters. Therefore, they do not test source water for chemicals such as glyphosate, endothall, or 2,3,7,8-tetrachlorodibenzo-p-dioxin (“Dioxin”). Bottled water sources must be tested for these chemicals annually, unless a state drinking water agency has specifically issued a waiver for the bottled water company’s ground water source. However, this does not occur frequently, as most bottled water sources are regulated by state agencies that regulate food products, not public water systems, and these agencies have no authority to issue those exemptions or waivers under FDA’s regulations. Bottled water finished products are not eligible for waivers, and must be tested annually. In contrast, a municipal water system groundwater system must collect only one or two post-treatment samples (depending on populations served) at the entry point into the distribution system for SOC analysis during each three-year monitoring period.

Radiological testing is required for both municipal water system ground water sources and for bottled water ground water sources. But, once again, there is a difference in frequency. Municipal water systems must test most radiological parameters once every four years. FDA, on the other hand, requires source water testing every four years, but finished product water must be tested annually.

Enforcement and Inspections

The FDA Standards of Identity and Standards of Quality apply to each container of bottled water. If a bottled water product contains a contaminant that exceeds an FDA “Standard of Quality”, the product must be labeled to reflect this substandard condition (e.g., “contains excessive _____”).²¹ Failure of a bottled water container to meet the standards of quality and to be properly labeled may subject it to recall by the company and removal from the market place. Further, and most importantly, if a bottled water product contains a contaminant that exceeds the Standard of Quality and it may be injurious to health, such product may be considered adulterated under the Federal Food, Drug, and Cosmetic Act (FFDCA) and subject to FDA enforcement action even if its label discloses the contaminant. The following tools are available to FDA in its enforcement of bottled water regulations:

- Pursuant to section 704 of the FFDCA (21 USC § 374), FDA may inspect any food manufacturing facility, including a bottled water plant.
- In the event a product is deemed misbranded or adulterated, FDA generally seeks voluntary compliance through the use of warning letters and requests for voluntary recalls.
- If the company declines to comply with applicable requirements or declines to take action to correct the violation, FDA may take civil action through either seizure or

²¹ 21 C.F.R. § 165.110(c), 21 U.S.C. § 343(h)(1)

- injunction. Depending on the circumstances, a criminal prosecution may also be warranted.²²
- FDA may also use its authority to warn the public (e.g., press releases) or to publicize a product recall.
 - Finally, under a new law passed just last year creating a reportable food registry, all food and beverage companies will be required to report to FDA whenever they have evidence showing a reasonable probability that their product may cause serious adverse health consequences or death, and FDA may take enforcement action if a company fails to do so.

FDA has increased the frequency of inspections of all food facilities and is working with state agencies with jurisdiction over food products through contracts to augment the FDA Office of Regulatory Affairs inspectors with state personnel. In addition, 24 states require out-of-state bottlers to be either licensed or permitted to do business in the state and as a condition to obtaining a permit, they require proof of inspection. The 26 states that do not require out-of-state bottlers to be permitted regulate the in-state bottlers and use either state or county inspectors to ensure compliance with the federal and/or state bottled water regulations.

Beyond these government inspection programs, IBWA requires its member bottlers to submit to an unannounced, independent third party inspection as a condition of membership. IBWA members are inspected for compliance with the IBWA Code of Practice, which include all FDA regulations as well as several more stringent requirements. The current inspection companies are Underwriter Laboratories (UL) and NSF International (NSF). IBWA bottler members must agree to a third party inspection by one of these two companies when they join or renew their membership. These third party inspection companies cannot participate in IBWA committees or policy development.

FDA Jurisdiction

FDA's jurisdiction over bottled water products (and any other product regulated by FDA) extends not only to those products that move in interstate commerce, but to those products sold within a single state that are enclosed in packaging materials that have moved in interstate commerce. Known as the component theory of FDA jurisdiction, courts have long held that if a component of a food product moves in interstate commerce, FDA has jurisdiction over the finished product, regardless of whether the finished product itself moves in interstate commerce. This is because it is a violation of the FFDCA to adulterate or misbrand a food while it is held for sale after shipping in interstate commerce.²³ This position is well established by judicial opinion.

For example, in United States v. An Article of Food, 752 F.2d 11 (1st Cir. 1985), FDA brought a seizure and condemnation action against three lots of bottled soft drinks on the premises of a beverage producer in Puerto Rico. FDA contended that the beverages were adulterated because

²² 21 U.S.C. § 333(a). Indeed, responsible officials of a food company may face criminal penalties for any violation of the FFDCA by the company, even if there was no “intent” to violate the law. *United States v. Park*, 421 U.S. 658 (1975).

²³ 21 U.S.C. § 331(k).

they contained an unapproved food additive (i.e., potassium nitrate). The bottler conceded that the beverages contained potassium nitrate but argued that FDA lacked jurisdiction because, although the potassium nitrate had been shipped in interstate commerce before addition to the beverages, the beverages had not. The court quickly disposed of the argument, commenting that “the ‘shipment in interstate commerce’ requirement is satisfied when adulterated articles held for in-state sale contain ingredients shipped in interstate commerce.”²⁴

The necessary interstate commerce element would likewise be satisfied based only on a component of a food product where the component is not edible, such as food packaging.²⁵ Indeed, IBWA is confident, based on the judicial precedent discussed above, that a court, if asked, would likely conclude that FDA has jurisdiction over bottled water if the bottle or other material used to package the water had been shipped in interstate commerce, even if the bottled water itself was processed and sold exclusively within the boundaries of a particular state.

Moreover, the FFDCRA was amended in 1997 to create a statutory presumption that all FDA-regulated products have traveled in interstate commerce. Thus, FDA no longer needs to establish the interstate commerce element to assert jurisdiction. 21 U.S.C. § 379(a) states, “In any action to enforce the requirements of this Act respecting a device, food, drug or cosmetic the connection with interstate commerce required for jurisdiction in such action shall be presumed to exist.”

Consumer Access to Bottled Water Information

IBWA supports a consumer’s right to clear accurate and comprehensive information about the bottled water products they purchase. IBWA agrees with the FDA’s conclusion that placing all this information on the product label is not feasible for many reasons including limited space

²⁴ An Article of Food, 752 F. 2d at 15 (citations omitted). This is only one in a long series of federal court decisions concluding that interstate shipment of a component of a food subjects the finished food to FDA jurisdiction. See also U.S. v. Sullivan, 332 U.S. 689 (1948) (labeling requirements of the Act apply to druggist who obtained drug product in bulk and repackaged it for intrastate sale where bulk product had previously moved in interstate commerce); U.S. v. Dianovin Pharmaceuticals, Inc., 475 F.2d 100 (1st Cir. 1973) (injectable form of vitamin K constituted drug held for sale after shipment in interstate commerce where components had moved in interstate commerce); United States v. Cassaro, Inc., 443 F.2d 153 (1st Cir. 1971) (finding bakers who sell bread and rolls made from flour shipped in interstate commerce are subject to prosecution for placing the flour in insect-contaminated equipment, thereby adulterating it); U.S. v. Detroit Vital Foods, Inc., 330 F.2d 78 (6th Cir. 1964) (finding misbranded tablets constituted drug held for sale after shipment in interstate commerce because ingredients had been shipped in interstate commerce); United States v. 40 Cases, More or Less, of Pinocchio Brand . . . Oil, 289 F.2d 343 (2d Cir. 1961) (concluding FDA has authority to proceed against misbranded or adulterated cans of vegetable oil that were mixed entirely within New York state from properly labeled oils shipped in interstate commerce), United States v. Varela-Cruz, 66 F. Supp. 2d 274 (D. Puerto Rico 1999) (rejecting defendants’ contention that FDA lacked authority to prosecute milk adulteration case because the salt used to economically adulterate milk had traveled in interstate commerce, thereby providing necessary interstate commerce element).

²⁵ Cf. Baker v. U.S., 932 F.2d 813, 814, 816 (9th Cir. 1991) (finding that “shipment in interstate commerce” occurs “even when only an ingredient is transported interstate” and that “whether the ingredient is a main one or a minor one . . . is inconsequential”); U.S. v. Miami Serpentarium Lab., Food Drug Cosm. L.J. (CCH 38, 164 (S.D. Fl. 1982) (finding federal jurisdiction even when the “interstate constituent comprises only a minute fraction of the article” and that “it is immaterial whether the ingredient is characterized as ‘active’ or ‘inactive.’”).

available.²⁶ IBWA believes the most feasible mechanism for consumers to obtain this information is through a request to the bottler or distributor.

IBWA believes that consumers should have timely and easy access to information about their bottled water products. To help ensure that consumers have access to useful and meaningful bottled water product information, the IBWA Code of Practice requires all members to comply with the following:

- All proprietary brand products must include a telephone number on their labels so consumers can easily contact the company and request product information.
- IBWA maintains an online member database, which also contains a specific link to a member company's water quality information and/or contact information that may be used to secure a company's water quality report.

IBWA offers counsel to bottlers as to how to prepare and present water quality reports. Such counsel is provided one-on-one with bottlers; in educational sessions at national, regional, or local bottled water industry meetings; and in monthly, weekly, and targeted publications. IBWA makes available to its members an online Water Quality Reporting Template, which users may download and enter extensive water quality reporting information based on analytical testing results for all regulated parameters.

IBWA provides either company contact information, a link to the company website for contact purposes or a direct link to water analysis data by brand on the IBWA website:
www.bottledwater.org

The current system of federal labeling laws and regulations protects the public health (including providing consumers with useful product information) and permits bottled water companies to sell their products in an efficient and cost effective manner in interstate commerce. All packaged foods and beverage products, including bottled water, have extensive labeling requirements, including a statement of identity, compliance with the applicable definitions in the Standard of Identity, ingredient labeling, name and place of business of the manufacturer, packer or distributor and if required, nutrition labeling. Any other information FDA may wish to require by regulation must be considered a material fact, the absence of which will result in misleading labeling for failure to reveal a material fact. Thus, if consumers are interested in more information about their choice of bottled water, they have the means to contact the manufacturer or distributor and request it.

Disclosures, such as those required by EPA in Consumer Confidence Reports for public water systems, are not required of any food or beverage product. These products must meet the safety standards and must be manufactured according to FDA regulations. . Bottled water has gone further than any other food or beverage product—including those beverages whose primary ingredient is water-- by voluntarily providing consumers with easy access to information about their products.

²⁶ 65 Fed. Reg. § 51836 (2000)

As mentioned earlier, consumers have a plethora of choices in brands of bottled water. That is not the case with their public water system. Consumers cannot make a choice of which municipal water is piped into their homes. If a bottled water company does not satisfy a consumer's request for more information, that consumer is free to make other brand choices. Such requests are not a matter of consumer safety because a bottled water product that does not meet the FDA Standards of Quality, which are the health-based standard for bottled water, may not stay in the market place and is subject to enforcement action by the FDA

Environmental Impact of Bottled Water

The bottled water industry is strongly committed to stewardship of the environment. Whether it is developing groundwater protection areas, supporting state groundwater management programs or developing new technology to reduce the plastic needed for its containers, the bottled water industry has been on the forefront of innovation in the food and beverage industry in developing policies and technology to promote environmental stewardship. IBWA is dedicated to the comprehensive management of bottled water packaging to provide the highest quality, cost effective and environmentally responsible containers possible. IBWA and its members approach packaging issues in a manner emphasizing the most effective and efficient solutions to reduce the impact on the environment, while taking into account the equal responsibility of all solid waste generators. Consideration must also be given to behavioral solutions, such as public education and enforcement of existing recycling and litter control laws.

Packaging

IBWA and its members believe a comprehensive approach must be utilized, emphasizing efficient and effective solutions that address the broad array of solid waste and treat all solid waste, including waste from all food and beverage products, in an equitable manner. IBWA believes the following set of principles should be a guide in addressing solid waste, recycling and litter:

- Education and awareness - Behavioral approaches to solid waste reduction and litter control must be a part of any good public policy.
- Efficient, yet effective, solutions - Programs that more properly balance cost and convenience with effectiveness should be given a higher priority.
- Curbside recycling programs – Improvements and expansion of curbside recycling and venue recycling opportunities need to be addressed.
- Equitable treatment for all waste producers - In order to effectively address the total municipal solid waste stream, proper solutions must look beyond just beverage containers.

Bottled water is one of thousands of food and beverage products that are packaged in plastic containers. Members of IBWA recognize their responsibility for their containers and are taking steps to mitigate its environmental impact. These steps will be outlined later in this testimony. However, the issue of environmental impact of plastic containers and the impact of those containers on community landfills is not solely to be borne by the bottled water industry, but

rather the producers of all consumer products. In addition, the debate must also include how do we, as a nation, increase the recycling rates and capture more of the plastic packaging for reuse. Plastic bottles that enter the recycling stream provide a valuable, sought after feedstock for numerous other consumer products.

The bottled water industry has one segment that has a uniquely positive story on reuse and recycling. The home and office delivery segment of the bottled water industry uses primarily three and five gallon plastic containers that are routinely returned, sanitized and reused from 20 to 40 times. The bottles are then sent by the bottler to be recycled. Almost 100% of these containers are first reused, and then recycled, and the processed plastic is made into a wide variety of different products. As indicated earlier in this testimony, the home and office delivery segment of the bottled water represents about 20% of the industry. IBWA is not aware of any other industry that experiences this incredible reuse and recycling rate.

For the retail market segment of the bottled water industry, the most common plastic used is PET, although HDPE and other plastics are used as well. These containers are fully recyclable and the value of the recycled plastic has been steadily increasing. However, bottled water is only one of many consumer products that use PET plastic in the production of the product.

To put the issue in perspective, in 2006 a total of 244 billion units of ready-to-drink beverages were sold, and only 33% of those units were packaged in plastic (see attached Chart I). A total of 36 billion units of bottled water were sold in 2006, amounting to only 15% of all beverage units sold. That means that 85% of all the beverage units sold in 2006 were for products *other than* bottled water. With regard to the lack of recycling of beverage units, bottled water critics claim that our products are filling up municipal landfills. Beverage containers are recycled at an overall rate of approximately 25%, a much higher rate than other food containers, and that rate continues to increase. Bottled water containers, as a subset of all beverage containers, has a recycling rate of approximately 21%. However, bottled water containers make up only 0.3% of the entire municipal waste stream in the United States (see attached Chart II). Clearly, bottled water containers are not significantly contributing to municipal landfills. Significant overall progress with recycling and the management of municipal waste streams cannot be made unless the public policy net is cast much more broadly than just bottled water. Efficiently capturing and recycling of *all* plastic products should be a priority.

The bottled water industry recognizes that the recycling rate for bottled water containers is not satisfactory. IBWA has joined with the American Beverage Association, the Food Marketing Institute, the Grocery Manufacturers Association and the National Recycling Coalition in the National Recycling Partnership to fund a pilot project in Hartford, Connecticut. The pilot project will measure the impact of having single stream collection with consumer financial incentives to recycle. The pilot project is utilizing Recycle Bank. Recycle Bank provides monetary credits on individual debit cards to each participating household for the amount that they recycle. We are hopeful that this project will demonstrate a means to increase community recycling rates, while lowering the impact on landfills. The project was launched in May of 2008, and we should see preliminary results before Thanksgiving. In addition, the Partnership joined with the United States Environmental Protection Agency (EPA) in funding research on rebranding recycling.

This is just one of many efforts in communities throughout the United States to increase the recycling rates.

More needs to be done. In 1999, almost 1000 communities around the country provided their citizens with curbside recycling. However, less than 900 communities offer this service today. Rather than fewer communities providing curbside recycling, more communities should be encouraged to establish curbside programs and promote recycling within their jurisdictions. We all can play a role in making this happen and the bottled water industry stands willing to work with others to enhance community recycling. Many of IBWA members donate bottled water to community events, such as fundraising efforts or community promotional events. They often condition the donation on the event sponsor providing recycling opportunities at the event.

As part of the environmental stewardship of the bottled water industry, innovations and new technologies are being developed to reduce the environmental impact of the industry. Two examples of such innovation can be seen in the container, itself. First, the PET bottled water container is produced using far less plastic than it did 10 years ago. The gram weight of plastic in a PET bottled water container is one of the lowest in the food industry. The lightest beverage container on the market is a bottled water container with less than 12.5 grams for a 500 ml container, as compared to many other beverage containers with over 20 grams of plastic. This has resulted in substantial decrease in plastic per container in the industry. This innovation is readily apparent to consumers as they can actually feel the difference in their bottled water container.

Second, new technologies are being developed to allow bottlers to use a “compostable” container made from corn. Bottled water is one of only a few food products that have begun to be packaged in this type of container, and a few IBWA members now use this type container for bottled water. Since it is relatively new to the market, the use of this new technology may increase over the next few years.

The bottled water industry should be recognized and supported in its efforts to innovate and find solutions to reducing the environmental impact of its product. Like all manufacturers of consumer goods, the industry is finding new ways to reduce the amount of petroleum used to deliver its product to market, whether using hybrid trucks or configuring delivery routes. These efforts are ongoing and vital to the continued economic health of the industry.

Water Stewardship

Groundwater is the primary water source for bottled water products sold in the United States. Because a long-term sustainable supply of high-quality water is literally the foundation and “lifeblood” of bottled water companies, IBWA member bottlers recognize the critical importance of environmental conservation and stewardship of all water resources. Bottled water companies perform hydro-geological assessments, monitor the quality and quantity at source wells, purchase surrounding land for protection and recharge of their source and participate in local and regional water stewardship partnerships on aquifer protection.

Groundwater is a renewable natural resource that is replenished through the hydrologic cycle. The duration of the replenishment cycle is influenced by weather patterns, recharge areas and characteristics, geologic settings and other site-specific factors. When developing and using water resources, it is essential that use is balanced with the replenishment cycle and the requirements of the regional demand for the resource. IBWA supports groundwater management policies, laws and regulations that are comprehensive, science-based, multi-jurisdictional, treat all users equitably, and balance the rights of current users against the future needs to provide a sustainable resource.

The bottled water industry uses minimal amounts of ground water to produce an important consumer product—and does so with great efficiency. According to a 2005 study by the Drinking Water Research Foundation (DWRf), annual bottled water production accounts for less than 2/100 of one percent (0.02%) of the total groundwater withdrawn in the United States each year.²⁷ Additionally, based on information gathered in the DWRf study, in 2001, 87% of the water withdrawn by bottled water companies, on average, was actually bottled for consumption by humans, so the bottling process is a very efficient one.²⁸

Bottled Water Plays a Vital Role in Disaster Response

Clean, safe water is a critical need for citizens and first responders immediately following a natural disaster or other catastrophic event. Unfortunately, the availability of water from public water systems is often compromised in the aftermath of such an event. During these times, bottled water is the best option to deliver clean safe drinking water quickly into affected areas.

The bottled water industry has always been at the forefront of relief efforts during natural disasters and other catastrophic events. Throughout the years, bottled water companies have immediately responded to the need for clean water after natural disasters, such as Hurricanes Andrew, Charlie, and Katrina, the earthquakes and forest fires in the West, or the terrorist attacks on the Pentagon and World Trade Center. More recently, our companies provided bottled water to those in need in the aftermath of the spring flooding in the Midwest, and in just the past two weeks to the victims of Hurricanes Gustav and Hanna.

The bottled water industry looks to IBWA to help coordinate activities with state and federal government agencies and organizations, such as the American Red Cross and Salvation Army. Working together, we determine the quickest and most effective way to deliver safe bottled water into affected areas to augment other relief efforts.

An example of this experience was the bottled water industry's response to the September 11, 2001, attacks on the Pentagon and World Trade Center. IBWA worked with the Salvation Army in identifying a staging area in Northern Virginia for bottled water being delivered to the Pentagon. The industry began shipping product to that staging area in the afternoon of

²⁷ Drinking Water Research Foundation, 2005, *Bottled Water Production in the United States: How Much Groundwater Is Actually Being Used?*

²⁸ Id.

September 11, 2001. In addition, IBWA identified one of its member companies' facilities on the western shore of the Hudson River as a staging area for bottled water being delivered across the river to “ground zero” in New York City. IBWA then notified its member bottlers of this location and they began shipping bottled water to the facility before the end of the day. IBWA also worked with the Federal Emergency Management Agency (FEMA) and National Guard so that bottled water and other goods could be staged at the facility and transported into New York City.

Another example is Hurricane Katrina, a tragic disaster that impacted millions of Americans. IBWA and its members were actively involved in responding to this monumental disaster. From IBWA members personally driving truckloads of bottled water and other relief supplies into affected areas, to shipments of multiple truckloads to remote communities—in many cases as the first responders on the scene—to the execution of staff/member partnerships to help identify and make arrangements with stricken communities for direct relief deliveries, the bottled water industry stepped up to the plate to donate products to those in need. IBWA members provided tens of millions of bottled water servings, ranging from 16-ounce bottles to five gallon bottled water cooler containers in the aftermath of Hurricane Katrina. This is in addition to the tankers of bulk drinking water supplied by IBWA bottlers and the tens of millions of servings provided through the relief organizations, state emergency management agencies and the Federal Emergency Management Agency.

Bottled water companies have also worked with municipal water systems to provide the public with clean, safe bottled water when the public drinking water infrastructure is compromised or when the water does not meet state and federal health standards. An example of such a situation occurred last year in Washington, DC, when lead levels in some parts of the public water supply exceeded the action level set by the United States Environmental Protection Agency (EPA). Bottled water and point-of-use systems were used to meet the drinking water needs in the affected area until the Washington Area Sanitation Commission was able to reduce the lead levels to meet EPA standards.

The efforts of the industry to provide crucial drinking water to citizens afflicted by disasters are contingent on a viable commercial market. The commercial market provides them with the capital and resources to respond when needed. The industry cannot exist only for disaster response as some industry critics would have people believe. The need for such philanthropic efforts can only be seen when people need it the most. To discourage the use of bottled water or question the safety of bottled water does a disservice to an industry that is called upon every year to provide much needed drinking water.

Conclusion

IBWA appreciates the opportunity to provide the Subcommittee with this overview of the bottled water industry. Bottled water provides consumers with a convenient, healthy beverage choice. The standards of quality for bottled water are as protective of public health as those for public drinking water by law and practice. Such standards for bottled water are applied to each container and failure to meet those standards may result in a recall or FDA enforcement action. If

a consumer is interested about what is in their bottled water, they have multiple methods of obtaining it, e.g., from the company website, contacting the company directly, researching state websites which post the information or IBWA's website, etc. If they are not satisfied with the response or the information provided, they have a plethora of choices among bottled water brands.

IBWA and its members are working with others to improve the recycling rates for plastic containers. The bottled water industry is committed to innovation and to reducing its environmental impact. IBWA will continue to work to increase the recycling rates for bottled water products. Finally, the near 100% reuse and recycling rate in the HOD segment of the bottled water industry is one of the "best kept secrets" that warrants broader awareness and recognition.

IBWA appreciates this opportunity to provide information on bottled water. If you would like more information or have further questions, please feel free to contact us.

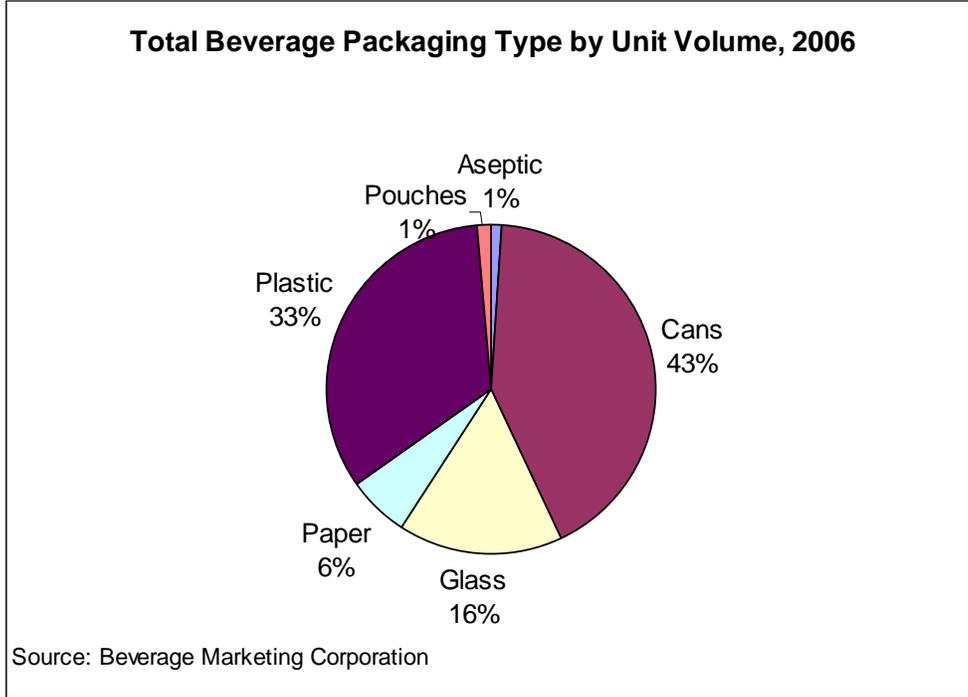


Chart I

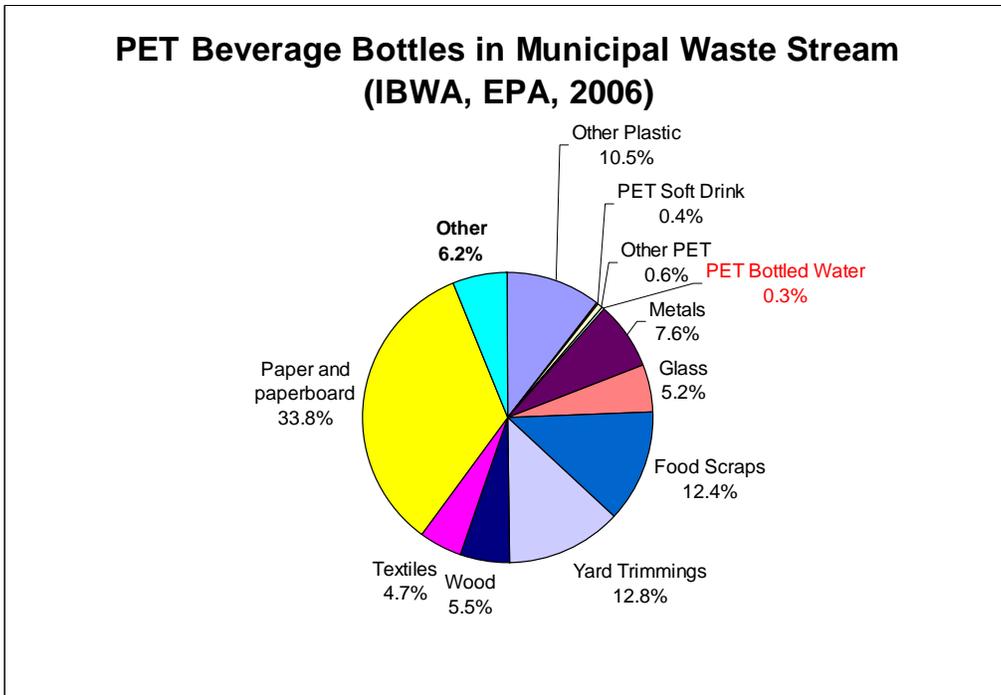


Chart II

Model Code



Bottled Water Code of Practice

Revised January, 2007

International Bottled Water Association
1700 Diagonal Road, Suite 650
Alexandria, VA 22314
(703) 683-5213
<http://www.bottledwater.org>

Appendix A

2007 MONITORING MATRIX

IBWA Model Code Monitoring Requirements

MONITORING PARAMETER GROUP		MONITORING FREQUENCY	SOQs, MCLs, SMCLs, and Guidelines (Apply to finished products)		
Individual Group Analytes			IBWA SOQ	FDA SOQ	EPA MCL
Inorganic Chemicals (IOCs)		ANNUALLY			
		(Product and Source)			
	Antimony (1)	For items with footnote (2), see <i>FDA D/DBP Rule Monitoring Requirements</i> on page 21.	0.006	0.006	0.006
	Arsenic		0.01	0.05	0.05
	Barium		1	2	2
	Beryllium (1)		0.004	0.004	0.004
	Bromate (2)		0.010	0.010	0.010
	Cadmium		0.005	0.005	0.005
	Chlorine (2)		0.1	4.0	4.0
	Chloramine (2)		4.0	4.0	4.0
	Chlorine dioxide (2)		0.8	0.8	0.8
	Chlorite (2)		1.0	1.0	1.0
	Chromium		0.05	0.1	0.1
	Cyanide (1)		0.1	0.1	0.2
	Fluoride		(3)	(3)	4
	Lead		0.005	0.005	0.015 AL
	Mercury		0.001	0.002	0.002
	Nickel (1)		0.1	0.1	
	Nitrate-N		10	10	10
	Nitrite-N		1	1	1
	Total Nitrate + Nitrite		10	10	10
	Selenium		0.01	0.05	0.05
	Thallium (1)	0.002	0.002	0.002	
Secondary Inorganic Parameters		ANNUALLY			
		(Product and Source)			
	Aluminum		0.2	0.2	0.2
	Chloride (5)		250	250	250
	Copper		1	1	1 AL
	Iron (5)		0.3	0.3	0.3
	Manganese (5)		0.05	0.05	0.05
	Silver		0.025	0.1	0.1
	Sulfate (5)		250	250	250
	Total Dissolved Solids (TDS) (5)		500	500	500
	Zinc (5)		5	5	5
Volatile Organic Chemicals (VOCs)			ANNUALLY		
		(Product and Source)			
	1,1,1-Trichloroethane	For items with footnote (2), see <i>FDA D/DBP Rule Monitoring Requirements</i> on page 21.	0.03	0.2	0.2
	1,1,2-Trichloroethane		0.003	0.005	0.005
	1,1-Dichloroethylene		0.002	0.007	0.007
	1,2,4-Trichlorobenzene		0.009	0.07	0.07
	1,2-Dichloroethane		0.002	0.005	0.005
	1,2-Dichloropropane		0.005	0.005	0.005
	Benzene		0.001	0.005	0.005
	Carbon tetrachloride		0.005	0.005	0.005
	cis-1,2-Dichloroethylene		0.07	0.07	0.07
	trans-1,2-Dichloroethylene		0.1	0.1	0.1
	Ethylbenzene		0.7	0.7	0.7
	Methylene chloride (Dichloromethane)		0.003	0.005	0.005
	Monochlorobenzene		0.05	0.1	0.1
	o-Dichlorobenzene		0.6	0.6	0.6
	p-Dichlorobenzene		0.075	0.075	0.075
	Haloacetic Acids (HAA5) (2)		0.06	0.06	0.06
	Styrene		0.1	0.1	0.1

- (1) Included in FDA's 9 contaminant regulations.
- (2) Included in FDA's D/DBP rule. See D/DBP monitoring requirements section on page 21 in Appendix A for details.
- (3) SOQ dependent upon temperature and other factors. See fluoride section on page 22 of Appendix A for details.
- (4) SMCL = Secondary maximum contaminant level. SMCLs are guidelines established by the USEPA for use in evaluating aesthetic, non-health-related properties in water. SMCLs are not enforceable for public water systems.
- (5) Mineral water is exempt from allowable level. The exemptions are aesthetically based allowable levels and do not relate to a health concern.

All SOQs, MCLs, SMCLs, and guidelines in mg/L (ppm) except as noted. Refer to your state bottled water regulations to determine if additional testing is required.

Appendix A

2007 MONITORING MATRIX

IBWA Model Code Monitoring Requirements

MONITORING PARAMETER GROUP		MONITORING FREQUENCY	SOQs, MCLs, SMCLs, and Guidelines (Apply to finished products)			
Individual Group Analytes			IBWA SOQ	FDA SOQ	EPA MCL	
Volatile Organic Chemicals (VOCs) (Continued)		ANNUALLY				
	Tetrachloroethylene	(Product and Source)	0.001	0.005	0.005	
	Toluene		1	1	1	
	Trichloroethylene	For items with footnote (2), see FDA D/DBP Rule Monitoring Requirements on page 21.	0.001	0.005	0.005	
	Vinyl chloride		0.002	0.002	0.002	
	Xylenes (total)		1	10	10	
	Bromodichloromethane		(6)	(6)	(6)	
	Chlorodibromomethane		(6)	(6)	(6)	
	Chloroform		(6)	(6)	(6)	
	Bromoform		(6)	(6)	(6)	
	Total Trihalomethanes (2)		0.01	0.08	0.08	
Semivolatile Organic Chemicals (SVOCs)			ANNUALLY			
	Benzo(a)pyrene		(Product and Source)	0.0002	0.0002	0.0002
	Di(2-ethylhexyl)adipate		0.4	0.4	0.4	
	Di(2-ethylhexyl)phthalate		0.006	NA	0.006	
	Hexachlorobenzene		0.001	0.001	0.001	
	Hexachlorocyclopentadiene		0.05	0.05	0.05	
	Total Recoverable Phenolics		0.001	0.001	NA	
Synthetic Organic Chemicals (SOCs)		ANNUALLY				
	2,4,5-TP (Silvex)	(Product and Source)	0.01	0.05	0.05	
	2,4-D (Dichlorophenoxy acetic acid)	(unless otherwise noted)	0.07	0.07	0.07	
	Alachlor		0.002	0.002	0.002	
	Aldicarb		0.003	NA	0.003	
	Aldicarb sulfone		0.003	NA	0.003	
	Aldicarb sulfoxide		0.004	NA	0.004	
	Atrazine		0.003	0.003	0.003	
	Carbofuran		0.04	0.04	0.04	
	Chlordane		0.002	0.002	0.002	
	Dalapon		0.2	0.2	0.2	
	Dibromochloropropane (DBCP)		0.0002	0.0002	0.0002	
	Dinoseb		0.007	0.007	0.007	
	Dioxin (2,3,7,8-Tetrachlorodibenzo-p-dioxin) (1)(7)	Product: Every 3 years Source: Annually	3x10 ⁻⁸	3x10 ⁻⁸	3x10 ⁻⁸	
	Diquat (1)(7)		0.02	0.02	0.02	
	Endothall (1)(7)		0.1	0.1	0.1	
	Endrin	ANNUALLY	0.002	0.002	0.002	
	Ethylene dibromide	(Product and Source)	0.00005	0.00005	0.00005	
	Glyphosate (1)(7)	Product: Every 3 years Source: Annually	0.7	0.7	0.7	
	Heptachlor	ANNUALLY	0.0004	0.0004	0.0004	
	Heptachlor epoxide	(Product and Source)	0.0002	0.0002	0.0002	
	Lindane		0.0002	0.0002	0.0002	
	Methoxychlor		0.04	0.04	0.04	
	Oxamyl (vydate)		0.2	0.2	0.2	
	Pentachlorophenol		0.001	0.001	0.001	
	Picloram		0.5	0.5	0.5	
	Polychlorinated biphenyls (PCBs)		0.0005	0.0005	0.0005	
	Simazine		0.004	0.004	0.004	
	Toxaphene		0.003	0.003	0.003	

(1) Included in FDA's 9 contaminant regulations.

(2) Included in FDA's D/DBP Rule. See D/DBP monitoring requirements section in Appendix A for details.

(6) No SOQs or MCLs established for individual trihalomethane contaminants. The sum of the 4 THMs is regulated as total trihalomethanes (TTHMs).

(7) FDA requires that the four synthetic organic chemicals (SOC) listed must be tested quarterly for four consecutive quarters for each type of finished bottled water (e.g., spring, purified, etc.). If none of the SOCs are detected, then once every three years for each type of finished product. If SOCs are detected, maintain monitoring for four consecutive quarters in each three-year period. New products and new companies must do an initial round of quarterly monitoring in the first year of operation.

All SOQs, MCLs, SMCLs, and guidelines in mg/L (ppm) except as noted. Refer to your state bottled water regulations to determine if additional testing is required.

Appendix A

2007 MONITORING MATRIX

IBWA Model Code Monitoring Requirements

MONITORING PARAMETER GROUP		MONITORING FREQUENCY	SOQs, MCLs, SMCLs, and Guidelines (Apply to finished products)		
Individual Group Analytes					
Additional Regulated Contaminants		ANNUALLY (Product and Source)	IBWA SOQ	FDA SOQ	EPA MCL
	Methyl tertiary butyl ether (MTBE)		0.07	NA	NA
	Naphthalene		0.3	NA	NA
	1,1,2,2-Tetrachloroethane		0.001	NA	NA
Microbiological Contaminants			IBWA SOQ	FDA SOQ	EPA MCL
	Total coliform / <i>E. coli</i>	SOURCE: at least once each week (21 CFR §129.35(a)(3)) PRODUCT: at least once each week (21 CFR §129.35(g)(1))	No <i>Escherichia coli</i> detectable in a 100 ml portion/sample. No validated total coliform detectable in a 100 ml portion/sample as substantiated by resampling. NOTE: Confirmation AND validation of all positive total coliform results in finished product required. See Appendix C of the Model Code.	MPN: <2.2 organisms per 100 ml. MF: <4 CFU per 100 ml.	No more than 5% of monthly samples valid for total coliform.
Radiological Contaminants		SEE BELOW	IBWA SOQ	FDA SOQ	EPA MCL
	Gross Alpha Particle Radioactivity	SOURCE: Annually	15 pCi/L	15 pCi/L	15 pCi/L
	Gross Beta Particle and Photon Radioactivity (8)	PRODUCT: Every 4 years	50 pCi/L	50 pCi/L	50 pCi/L
	Radium 226/228 (combined)	SOURCE: Annually PRODUCT: Every 4 years	5 pCi/L	5 pCi/L	5 pCi/L
	Uranium	SOURCE: Annually PRODUCT: Every 4 years	0.030	0.030	0.030
Water Properties		ANNUALLY (Product and Source)	IBWA SOQ	FDA SOQ	GUIDELINE
	Color		5 Units	15 Units	5 Units
	Turbidity		0.5 NTU	5.0 NTU	0.5 NTU
	pH (9)		5-7/6.5-8.5	NA	6.5-8.5
	Odor		3 T.O.N.	3 T.O.N.	3 T.O.N.

(8) If the gross beta particle activity exceeds 50 pCi/l, an analysis of the sample must be performed to identify the major radioactive constituents present. Compliance (with § 141.16) may be assumed without further analysis if the average annual concentration of gross beta particle activity is less than 50 pCi/l and if the average annual concentrations of tritium and strontium-90 are less than those listed in table A, *Provided*, That if both radionuclides are present the sum of their annual dose equivalents to bone marrow shall not exceed 4 millirem/year. Consult with your testing laboratory for more information.

(9) The Model Code guideline for pH in purified water is 5.0-7.0 (see Appendix B for definition and requirements for purified water). The guideline for source water and other product waters is 6.5-8.5. NOTE: This guideline is not enforceable.

All SOQs, MCLs, SMCLs, and guidelines in mg/L(ppm) except as noted. Refer to your state bottled water regulations to determine if additional testing is required.

Appendix A

2007 MONITORING MATRIX

IBWA Model Code Monitoring Requirements

FDA D/DBP Rule Monitoring Requirements

Public Water System (PWS) Source Water

If current PWS D/DBP data is available, no source water analysis is required.

If current PWS D/DBP data is NOT available, ANNUAL testing for the following is required:

- Disinfectants: Chlorine, Chloramine, Chlorine dioxide
- Disinfection Byproducts: Bromate, Chlorite, Haloacetic acids (HAA5), and Total Trihalomethanes (TTHMs)

Natural Water Sources

If no disinfection is applied at the source, including use in bulk water hauling, no source water analysis is required.

If disinfection is applied at the source, including use in bulk water hauling, ANNUAL testing for the following is required:

- The residual disinfectant used (chlorine, chloramine, or chlorine dioxide)
- Ozone: Bromate, Haloacetic acids (HAA5), Total Trihalomethanes (TTHMs)
- Chlorine-based disinfectants (chlorine, chloramine, or chlorine dioxide): Haloacetic acids (HAA5) and Total Trihalomethanes (TTHMs)

ALL FINISHED PRODUCTS

ANNUAL testing is required for ALL of the following in each finished product type:

- Chlorine
- Chloramine
- Chlorine dioxide
- Bromate
- Chlorite
- Haloacetic acids (HAA5)
- Total Trihalomethanes (TTHMs)

Appendix A

2007 MONITORING MATRIX

IBWA Model Code Monitoring Requirements

FDA Requirements for Fluoride in Bottled Water

Bottled water packaged in the United States to which no fluoride is added shall not contain fluoride in excess of the levels in Table 1 and these levels shall be based on the annual average of maximum daily air temperatures at the location where the bottled water is sold at retail.

TABLE 1

<u>*Annual average of maximum daily air temperatures (°F)</u>	<u>Fluoride concentration in milligrams per liter</u>
53.7 and below	2.4
53.8–58.3	2.2
58.4–63.8	2.0
63.9–70.6	1.8
70.7–79.2	1.6
79.3–90.5	1.4

Imported bottled water to which no fluoride is added shall not contain fluoride in excess of 1.4 milligrams per liter.

Bottled water packaged in the United States to which fluoride is added shall not contain fluoride in excess of levels in Table 2 and these levels shall be based on the annual average of maximum daily air temperatures at the location where the bottled water is sold at retail.

TABLE 2

<u>*Annual average of maximum daily air temperatures (°F)</u>	<u>Fluoride concentration in milligrams per liter</u>
53.7 and below	1.7
53.8–58.3	1.5
58.4–63.8	1.3
63.9–70.6	1.2
70.7–79.2	1.0
79.3–90.5	0.8

Imported bottled water to which fluoride is added shall not contain fluoride in excess of 0.8 milligram per liter.